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10/552,460

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Alberto Sardo

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2270

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7590

08/19/2009

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EXAMINER

GWARTNEY, ELIZABETH A

ART UNIT

PAPER NUMBER

1794

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,460	<b>Applicant(s)</b> SARDO, ALBERTO	
	<b>Examiner</b> Elizabeth Gwartney	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-43, 47, 48, 54 and 56-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-43, 47, 48, 54 and 56-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/03/2009 has been entered.
2. Claims 44-46, 49-53 and 55 have been cancelled and claims 72-73 have been added. Claims 39-43, 47-48, 54, and 56-73 are pending.
3. The previous 112 2<sup>nd</sup> Paragraph rejections have been withdrawn in light of applicant's amendments made 08/03/2009.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 39-43 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia-Mina et al. (EP 1 106 070 A2).

Regarding claims 39 and 72-73, Garcia-Mina et al. disclose a method for controlling post-harvest pathology of fruits and vegetables (i.e. affliction of pathogenic agents and processes of chemical degeneration of the skin) comprising applying a composition containing an active ingredient selected from eugenol, terpineol, and geraniol and a surface active including lecithin (Abstract, [0001], [0016], and [[0019]). Garcia-Mina et al. disclose a composition wherein the surface active is in an aqueous solution (i.e. composition including water-[0035]/Formula 1, [0042]/Formula 2) and diluted (*see* in a bath, diluted, concentration: 200-1000 ppm - [0032], claims 4-5. Garcia-Mina et al. also disclose that the composition dose is between 1 and 10000 ppm ([0019]/L13). Garcia-Mina et al. disclose a composition comprising between 10% and 30% surface active compound (see preparation of 1 kg. product – [0031], claim 3) that is known under the tradename Twen 80 and or Span 80). While there is no explicit disclosure regarding the amount of lecithin, given that Garcia-Mina disclose the equivalence and interchangeability of

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using lecithin with using Twen 80 ([0019]), it would have been obvious to one of ordinary skill in the art to also use lecithin in amount of between 0.1 and 3300 ppm.

Garcia-Mina et al. also disclose that the lecithin is applied to the fruit at a concentration of about 0.1 ppm to about 3000 ppm (given product is treated in a solution of 1 to 10000 ppm concentration wherein 10-30% of the solution comprises lecithin - claims 3-4).

Regarding claims 40-41, Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the lecithins contain 30% to 60% lysolecithins. A skilled artisan would know that the hydrolyzed form of lecithin, lysolecithin, has superior emulsification properties to lecithin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced a portion, including between 30% and 60% of all of the lecithin, in the composition of Garcia-Mina et al. with lysolecithin for the purpose of making a more stable emulsion with the treatment agent ingredient.

Regarding claim 42, Garcia-Mina et al. disclose all of the claim limitations as set forth above. Since Garcia-Mina et al. disclose lecithin ([0019]), the limitations of this claim have been met.

Regarding claim 43, Garcia-Mina et al. disclose all of the claim limitations as set forth above and that the treatment agents and lecithin are formulated to be administered simultaneously ([0019]).

Regarding claim 65, Garcia-Mina et al. disclose a method for treating fruits and vegetables comprising bathing the fruits and vegetables at a temperature of 45° to 50°C in a composition comprising lecithin ([0019], [0032]). Garcia-Mina et al. also disclose an aqueous solution comprising lecithin (i.e. composition including water-[0035]/Formula 1, [0042]/Formula

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2) and diluting the solution prior to bathing fruits and vegetables (*see* in a bath , diluted, concentration: 200-1000 ppm - [0032], claims 4-5). Garcia-Mina et al. also disclose that the composition dose is between 1 and 10000 ppm ([0019]/L13). Garcia-Mina et al. disclose a composition comprising between 10% and 30% surface active compound (see preparation of 1 kg. product – [0031], claim 3) that is known under the tradename Twen 80 and or Span 80).

While there is no explicit disclosure regarding the amount of lecithin, given that Garcia-Mina disclose the equivalence and interchangeability of using lecithin with using Twen 80 ([0019]), it would have been obvious to one of ordinary skill in the art to also use lecithin in amount of between 0.1 and 3300 ppm.

8. Claims 47-48, 54, 56-64 and 66-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia-Mina et al. (EP 1 106 070 A2) in view of Schur (US 6,514,551).

Regarding claims 47 and 54, Garcia-Mina et al. disclose a composition containing one or more treatment agents for fruits and vegetables and lecithin (Abstract, [0019]). Specifically, Garcia-Mina et al. also disclose a composition that comprises 15% eugenol, 20% surface-active complex (i.e. lecithin - [0019]), and 25% water ([0035]).

While Garcia-Mina et al. disclose a composition dissolved in an aqueous base and diluted with water, the reference does not explicitly disclose that the composition is dissolved in 30% to 60% vegetable oil.

Schur teaches a composition for impacting the surface of microbially perishable products comprising a microbicidally active substance and lecithin diluted in vegetable oil (C2/53-54, C6/L3-6, C9/L24-30,46-53).

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Garcia-Mina et al. and Schur are combinable because they are concerned with the same field of endeavor, namely, stabilization of microbially perishable products. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have used vegetable oil, as taught by Schur, to dilute the composition of Garcia-Mina et al. because doing so would amount to nothing more than the use of a known food grade dilutant for its intended use in a known environment to accomplish entirely expected results.

As fluidity and ease of application are variables that can be modified, among others, by adjusting the amount of vegetable oil base, the precise amount of vegetable oil base would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of vegetable oil cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of vegetable oil in the composition of modified Garcia-Mina et al. to obtain the desired fluidity and application efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 48, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agents and lecithin are formulated in order to be administered simultaneously ([0019]).

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Regarding claims 56-57, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the ratio of lecithin to the treatment agent is about 1.3 (*see* 20% surface active complex (i.e. lecithin-[0019]) to 15% eugenol – [0035]).

Regarding claim 58, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the lecithin contains between 5% and 15% lysolecithin. A skilled artisan would know that the hydrolyzed form of lecithin, lysolecithin, has superior emulsification properties to lecithin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced a portion, or all of the lecithin, in the composition of modified Garcia-Mina et al. with lysolecithin for the purpose of making a more stable emulsion with the treatment agent ingredient.

Regarding claim 59, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose applying the composition to fruits and vegetables (Abstract, [0032]).

Regarding claim 60, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is diluted in water to a dose between 1 and 10000 ppm ([0019], [0032]).

Regarding claim 61, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is diluted in water and applied at a temperature of from 45° to 50°C ([0032]).

Regarding claims 62-63, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is applied by mean of



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showering or immersion ([0019]/L11-12). Garcia-Mina et al. also disclose use of the composition post-harvest ([0016]/L37).

Regarding claim 64, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the application of the composition is carried out before harvesting the fruit or vegetable. Given that the composition is used to control post-harvest pathologies, it would have been obvious to a skilled artisan to have applied the composition to the fruit or vegetable at any time prior to distribution and achieve the same benefits.

Regarding claim 66, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. While Schur teaches mixing lecithin and a microbicidally active substance (i.e. eugenol) in a vegetable oil base, the reference does not explicitly teach adding lecithin to the vegetable oil base followed by addition of the active substance. To switch the order of performing process steps, i.e. the order of the addition of the ingredients into the final composition, would be obvious absent any clear and convincing evidence and/or arguments to the contrary (MPEP 2144.04[R-1]). "Selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results."

Regarding claim 67, Garcia-Mina et al. disclose a method for controlling post-harvest pathology of fruits and vegetables (i.e. affliction of pathogenic agents and processes of chemical degeneration of the skin) comprising mixing a composition containing an active ingredient selected from eugenol, terpineol, and geraniol and a surface active including lecithin (Abstract, [0001], [0016], [0019]) in an aqueous base (*see* [0035]/Formula 1 and [0042]/Formula 2).

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Garcia-Mina does not disclose that the lecithin and treatment agents are mixed in an oil base or that the method is for preserving lecithins and/or derivatives thereof.

Schur teaches a composition for impacting the surface of microbially perishable products comprising a microbicidally active substance and lecithin diluted (i.e. mixed) in vegetable oil (C2/53-54, C6/L3-6, C9/L24-30,46-53).

Garcia-Mina et al. and Schur are combinable because they are concerned with the same field of endeavor, namely, stabilization of microbially perishable products. I would have been obvious to one of ordinary skill in the art at the time of the invention was made to have mixed the treatment agent and lecithin in Garcia-Mina et al, with vegetable oil, as taught by Schur, because doing so would amount to nothing more than the use of a known food grade dilutant for its intended use in a known environment to accomplish entirely expected results.

The recitation that says the method is for preserving lecithins does confer patentability to the claim since statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

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Regarding claim 68, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent has fungicidal properties ([0002]/L8).

Regarding claim 69, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent is eugenol (Abstract, [0019]).

Regarding claims 70-71, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent represents 40% by weight of the lecithin (*see* preparation of 1 kg. product where eugenol is 40% of the surface active substance – [0031]).

### ***Response to Arguments***

9. Applicant's arguments filed 08/03/2009 have been fully considered but they are not persuasive.

Applicants argue that Garcia-Mina et al. is totally silent with respect to the formulation of the lecithin, rather Garcia-Mina et al. merely discloses a surface active such as lecithin. Further, applicants find that the reference composition comprises neither an oil base nor water and is not formulated as a premix in water or oil prior to dilution and application as required by instant claim 39. Finally, applicants find that Garcia-Mina et al. does not disclose a lecithin concentration of between 100 and 5000 ppm in claim 39.

Garcia-Mina et al. disclose a "premix" composition comprising a main active ingredient, secondary active ingredients, a surface active, oligosaccharides and water (claim 3,

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[0035]/Formula 1, [0042]/Formula 2). Garcia-Mina et al. further discloses diluting the composition to provide a solution of 1 to 10,000 ppm concentration for treating the fruits and vegetables (claim 4, [0032] – “in a diluted bath” “concentration: 200-1000 ppm”). Further, Garcia-Mina et al. disclose a composition comprising 10% to 30% surface active compound, (see preparation of 1 kg. product – [0031], claim 3) that is known under the tradename Twen 80 and or Span 80). While there is no explicit disclosure regarding the amount of lecithin, given that Garcia-Mina disclose the equivalence and interchangeability of using lecithin with using Twen 80 and Span 80 ([0019]), it would have been obvious to one of ordinary skill in the art to also use lecithin in amount of between 0.1 and 3300 ppm.

Applicants argue that Mulder does not disclose the step of formulating the lecithin and/or derivative in an aqueous solution or in a vegetable oil. The reference merely discloses the step of formulating the lecithin in an organic solvent, and not in water or vegetable oil.

Applicant's arguments with respect to claims 39 and 42-44 rejected with Mulder (US 3,451,826) in view of Garcia-Mina et al. (EP 1 106 070 A2) have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that “[n]othing in Garcia-Mina et al. nor in Mulder would have led the skilled person to achieve such a method with outstanding results as shown by the experimental data presented with the Rule 132 Declaration filed June 3, 2009.”

Applicants allege unexpected results based on evidence presented in a Declaration under Rule 132 filed 06/03/09. The question as to whether unexpected advantage has been demonstrated is a factual question. *In re Johnson*, 747 F.2d 1456, 1460, 223 USPQ 1260, 1263 (Fed. Cir. 1984). Thus, it is incumbent upon applicant to supply the factual basis to rebut the

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prima facie case of obviousness established by examiner. See, e.g., *In re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972). Applicants, however, do not provide an adequate explanation regarding any factual showing in the specification of unexpected results as data has not been shown to be commensurate in scope with rejected claims. For example, neither of the claims rejected under Mulder and Garcia-Mina et al. are limited to eugenol as a chemical treatment agent. Nor have the applicants shown that comparison samples in said Declaration fairly represent the closest prior art. Further, the data is not persuasive given that Garcia-Mina already discloses the criticality of using a surface active including lecithin with eugenol.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday; 7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794